Amendments to the Drawings:

Cancel the first sheet of drawings and substitute therefor the new sheet of drawings enclosed.

REMARKS

Petition is hereby made under the provisions of 37 CFR 1.136(a) for an extension of three months of the period for response to the Office Action. Authorization to charge the prescribed fee to our deposit account is enclosed.

The informalities noted by the Examiner on pages 5 and 21 have been corrected. In addition, page 1 has been amended to refer to the precursor application.

With respect to the use of trade-marks, the terms "TRITON" and "FLUZONE" have been capitalized at the various locations throughout the disclosure. Generic terminology is included in the disclosure with respect to both trade-marks.

The Examiner objected to the drawings with respect to the use of the legend "Flu/RSV + PCP" in lane (g) of Figure 1. This legend has been corrected to "Flu/RSV + PCPP".

The Examiner rejected claims 1 to 20 under 35 U.S.C. 112, first paragraph, on the basis that the specification, while enabling for compositions and methods of inducing an anti-RSV immune response in humans, does not reasonably provide enablement for compositions effective for conferring protection or methods of immunizing humans against RSV infection.

Claims 1 and 18 have been amended to define a composition and method for generating an immune response to RSV. It is submitted that the claims are fully enabled by the disclosure and hence the rejection of claims 1 to 20 under 35 U.S.C. 112, first paragraph, for counting enablement, should be withdrawn.

The Examiner rejected claim 4 under 35 U.S.C. 112, first paragraph, for failing to comply with the written description requirement. The Examiner considered that the claim contained subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art

that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In particular, the Examiner indicated that the claim was rejected as lacking sufficient written descriptive support for compositions comprising any adjuvant or any inactivated influenza preparation with any mixture of RSV F, G and M antigens such that the desired anti-RSV enhancement is achieved. In this respect, the subject matter of claim 5, reciting the adjuvant as being PCPP, has been incorporated into claim 4 with claim 5 being deleted. In addition, the subject matter of claim 2 has been incorporated into claim 1, with claims 2 and 19 being deleted. Claim 3 was been made dependent on claim 1.

It is submitted that claim 4 now complies with the written description requirement of 35 U.S.C. 112, first paragraph, and hence the rejection thereof under 35 U.S.C. 112, first paragraph, on civis ground, should be withdrawn.

The Examiner rejected claims 1 to 20 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly provide point out and distinctly claim the subject matter which applicant regards as the invention, with respect to the use of the term "immunoeffective amount" in claims 1 and 18. The Examiner's suggestion for removal of this term from claims 1 and 18 has been adopted. It is submitted that all claims can no longer be considered to be indefinite and hence the rejection of claims 1 to 20 under 35 U.S.C. 112, second paragraph, should be withdrawn.

The Examiner rejected claims 1 to 3 and 6 to 19 under 35 U.S.C.103(a) as being unpatentable over Cates et al U.S. Patent No. 6,020,182, in view of Smith U.S. Patent No. 5,762,939 and Webster et al U.S. Patent No. 5,824,536.

The Cates et al reference is relied on for a teaching of a RSV preparation corresponding to component (a) of the composition of claim 1 and for a teaching of immunostimulation of such composition using an adjuvant. As the

Examiner states, the reference indicates that the immunogenic compositions provided in Cates et al may be formulated to comprise at least one additional immunogen. Among the veritable shopping list of immunogens is mentioned influenza.

There is no motivation to select influenza from the list of pathogens contained in Cates, nor is there any expectation that formulating influenza with the RSV preparation will not result in lack of impairment of the immunogenicity of the individual components of the composition.

The Examiner relies on Smith et al reference for a teaching related to influenza virus vaccine. The Examiner asserts that this disclosure renders obvious the use of non-virulent influenza composition in the composition taught by Cates et al. However, as noted above, there is no motivation to select the influenza virus and no knowledge as to whether or not the immunogenicities of the components of the composition would be impaired, if the Smith et al compositions were used with the Cates et al RSV preparation. Applicants have found that, when a non-virulent influenza virus preparation is selected, then there is no impairment of the respective immunogenicities.

While, as the Examiner states, the art of vaccination recognized the value of combining treatments so as to simplify the vaccination process, however, it is equally true that the art of vaccination recognized that the potential for impairment of the immunogenicity would arise in any new combination of immunogens. The applicants have found that there is no such impairment of immunogenicity when combining the RSV protein preparation with a non-virulent influenza virus preparation.

Although the Examiner included the Webster et al reference in the rejection, there is no discussion of this reference in the rejection. It is, therefore, not possible to comment on the features of the Webster et al reference that might be relied on.

Accordingly, it is submitted that claims 1 to 3 and 6 to 18 are patentable over the applied combination of prior art and hence the rejection thereof under 35 U.S.C. 103(a) as being unpatentable over Cates et al (Cates US) in view of Smith et al and Webster et al, should be withdrawn.

The Examiner rejected claims 1 to 3 and 6 to 18 under 35 U.S.C. 103(a) as being unpatentable over Cates et al WO 98/02457 (Cates PCT) in view of Smith et al and Webster et al.

The Cates PCT publication contains the same disclosure as the Cates U.S. Patent discussed above with respect to the previous prior art rejection. The rejection, therefore, appears to be merely cumulative of the prior rejection. In any event, the same observations apply to this rejection as to the rejection based on Cates U.S. and the same distinctions also apply.

Accordingly, it is submitted that claims 1 to 3 and 6 to 19 are patentable over the applied combination of prior art and hence the rejection thereof under 35 U.SD.C. 103(a) as being unpatentable over Cates PCT in view of Smith et al and Webster et al, should be withdrawn.

The Examiner rejected claims 1 to 3 and 5 to 19 under 35 U.S.C. 103(a) as being unpatentable over Cates US or Cates PCT in view of Smith and Webster, as applied to claims 1 to 3 and 6 to 18 and further in view of Payne. The combination of Cates US or Cates PCT in view of Smith et al and Webster et al references, have been discussed above.

As the Examiner indicates, claim 5 limits the adjuvant of claim 4 to PCPP. As noted above, claim 5 has now been incorporated into claim 4. As discussed by Payne, PCPP is a known immunoadjuvant. However, applicants rely for the patentability of claim 4 on its dependency on claim 1 and the demonstrated patentability of claim 1 over the disclosures of Cates PCT and Cates US in view of Smith et al and Webster et al.

Accordingly, it is submitted that claims 1 to 3 and 5 to 29 are patentable over the applied art and hence the rejection thereof under 35 U.S.C. 103(a) as being unpatentable over Cates US or Cates PCT in view of Smith et al and Webster et al and further in view of Payne, should be withdrawn.

The Examiner rejected claims 1 to 3 and 6 to 19 under 35 U.S.C. 103(a) as being unpatentable over Cates US or Cates PCT, as applied to claims 1 to 3 and 6 to 18, and further in view of Huebner. It is unclear whether the Examiner intended to include Smith et al and Webster et al in this rejection. In any event, the applicants have demonstrated above that the claims are patentably distinguish over this combination. Huebner describes the split virus vaccine Fluzone and the processing thereof to obtain intact HA protein and formation of immunogenic conjugates therefrom.

The Huebner reference is no more relevant to the present invention than the Smith et al reference discussed above. For the reason that the Smith et al reference and the Cates US or Cates PCT references cannot be combined, the Huebner reference too cannot be combined with Cates US or Cates PCT.

Accordingly, it is submitted that claims 1 to 3 and 6 to 19 are patentable over the applied prior art and hence the rejection thereof under 35 USC 103(a) as being unpatentable over Cates US or Cates PCT and further in view of Huebner, should be withdrawn.

The Examiner rejected claim 20 under 35 USC 103(a) as being unpatentable over Cates US or Cates PCT in view of Smith and Webster, or in view of Huebner and further in view of Potash.

The Potash reference apparently is relied on for a disclosure that RSV and influenza virus infections may occur throughout the adult life of a person. However, the patentability of claim 20 relies on the patentability of claim 1 over the applied combinations of prior art for the reasons discussed above.

Accordingly, it is submitted that claim 20 is patentable over the applied art and hence the rejection thereof under 35 USC 103 (a) as being unpatentable over Cates US or Cates PCT in view of Smith and Webster or in view of Huebner, and further in view of Potash, should be withdrawn.

The Examiner rejected claims 1 to 3 and 5 to 17 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 to 9 and 13 of U.S. Patent No. 6,020,182 in view of Smith, Webster, Payne and Potash. Each of these references has been discussed above in connection with various rejections under 35 U.S.C. 103(a) based thereon. Having regard to this discussion, it is submitted that claims 1 to 3 and 5 to 17 do not represent an obviousness-type double patenting with respect to this combination of prior art and hence the rejection thereof under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 to 9 and 13 of Cates U.S. Patent No. 6,020,182 in view of Smith, Webster, Payne and Potash, should be withdrawn.

The Examiner rejected claims 1 to 3 and 5 to 17 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2 and 6 to 16 of Cates U.S. Patent No. 6,309,649 in view of Smith, Webster and Payne. The Smith, Webster and Payne references have been discussed above with reference to the various rejections under 35 U.S.C. 103(a). The Cates U.S. Patent No. 6,309,649 is a continuation-in-part of Cates U.S. Patent No. 6,020,182 and contains no disclosure more relevant than that discussed above with respect to Cates 6,020,182.

Having regard thereto, it is submitted that claims 1 to 3 and 5 to 17 do not represent on obviousness-type double patenting with respect to this combination of prior art and hence the rejection thereof under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2 and 6 to 16 of U.S. Patent No. 6,309,649 in view of Smith, Webster and Payne, should be withdrawn.

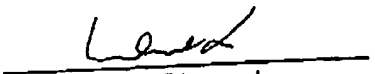
The Examiner provisionally rejected claims 1 to 3 and 5 to 17 on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1 to 4 and 9 to 11 of copending Application No. 10/467,828 in view of the teachings of Cates PCT, Smith, Webster and Payne. The rejection is a provisional one since the conflicting claims have not yet been patented. No action, therefore, is required to be taken at the present time with respect to this rejection.

The Examiner provisionally rejected claims 1 to 3 and 5 to 20 on the grounds of non-statutory obviousness-type double patenting as being unpatentable over claims 1, 2 to 7, 9, 12 to 21, 23, 24 and 36 of copending Application No. 10/488,421 in view of Smith, Webster, Payne and Potash. The rejection is a provisional one since the conflicting claims have not proceed to grant. No action, therefore, is required to be taken at the present time with respect to this rejection.

The Examiner provisionally rejected claims 1 to 20 on the ground of the non-statutory obviousness-type double patenting as being unpatentable over claims 3, 5 to 14, 20 and 21 of copending Application No. 09/868,177. The rejection is a provisional one since the conflicting claims have not yet been patented. Accordingly, there is no action that needs to be taken at the present time with respect to this rejection.

It is believed that this application is now in condition for allowance and early and favourable consideration and allowance are respectfully solicited.

Respectfully submitted,



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